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(54) Method and arrangement for evaluating effective flow resistance of a patient breathing circuit

(57) An arrangement for evaluating an effective flow resistance of a breathing circuit (4) connected to a mechanical breathing assist device (2), the arrangement comprises:
a flow controller (8,28) operable to temporarily introduce an occlusion to gas flow within the breathing circuit (4) at a time after the end of an inspiration phase of a breathing cycle provided by the breathing assist device (2); a sensor unit 34 having a flow sensor for measuring gas flow within the circuit (4) and a pressure sensor for measuring gas pressures within the circuit (4); and an evaluating unit (6) adapted to receive measurements from the sensor unit (34), to determine for a measured gas flow a value of a pressure drop within the breathing circuit (4) consequent on the introduction of the occlusion and to establish a relationship between the calculated pressure drop and the measured gas flow, preferably based on the known Blasius formula.

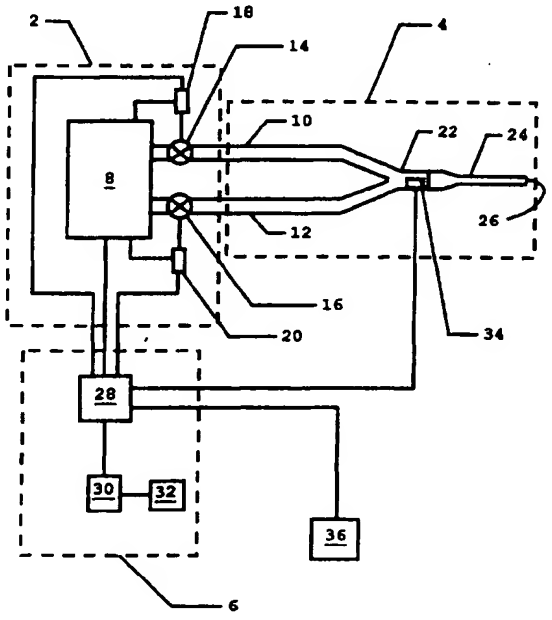

Fig. 1

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Description

[0001] The present invention relates to a method for evaluating the effective flow resistance of a patient breathing circuit during mechanical breathing assistance and to a device for carrying out the method.

[0002] Providing mechanical breathing assistance to a patient is a well known medical procedure and is most often used in surgical and critical care situations. Typically, a breathing tube, such as an endotracheal or a tracheotomy tube, is inserted into the patient's trachea so that the distal end of the tube is disposed in the patient's airways and the proximal end is accessible external the patient. The proximal end connects with a gas tubing system, typically by means of a Y-Piece connector, to form a breathing circuit which in turn connects with a breathing assist device. The breathing assist device, such as a ventilator, respirator or anaesthetic delivery system, is adapted to control the flow of gas through the breathing circuit to and from the patient's airways and thereby regulate the patient's breathing cycle.

[0003] Over-pressurisation of the breathing gas provided to the patient through the breathing tube can cause barotrauma and so the gas pressure within the breathing circuit is usually monitored and used to control the assist device. Pressure sensors are typically provided within the assist device itself or at the Y-piece to monitor the gas pressures at the proximal end of the breathing tube. However, because the breathing tube has a relatively narrow bore compared with the rest of the breathing circuit the breathing tube offers a large resistance to gas flow. This leads to inaccuracies between the pressures registered by the sensors and those extant within the lungs so that barotrauma may still occur due to too high a delivery pressure of the breathing gas. In other circumstances the delivery pressure of the breathing gas may be adjusted to too low a level so that efficient opening of the lungs no longer occurs.

[0004] In order to reduce the effects of the flow resistance of the breathing circuit (principally the delivery tube) on the safe and effective operation of the assist device it is known to adapt the device to compensate the sensed delivery pressure for the breathing tube resistance and to use this compensated pressure value to control the delivery of breathing gas. In the known device this is done by a user inputting information relating to the breathing tube's resistance before the breathing assistance is started. This information may be in the form of the tube's length and internal diameter, from which a theoretical resistance can be calculated, or can be an actual calculated or measured resistance value determined before use.

[0005] One problem with this is that there exists a possibility that the user may input the information incorrectly. Another problem is that the resistance provided in the known manner may not be the true resistance of the tube since this may vary throughout the operation of the device or as a result of the initial placement of the tube within the patient's trachea.

[0006] It is an aim of the present invention to provide a method and an arrangement for carrying out the method, the use of which makes it possible to alleviate at least one of the problems associated with the known breathing assist device.

[0007] According to a first aspect of the present invention there is provided a method for evaluating an effective flow resistance of a breathing circuit during mechanical breathing assistance as described in and characterised by the present claim 1.

[0008] The determined pressure drop at the onset of an occlusion may be assumed to effectively result from the resistance of a patient breathing tube which is present within the breathing circuit since the diameter of the tube is much smaller than the diameter of any other tubing component of the circuit and an indication of the tube resistance may be established from a pressure drop/flow relationship, which to a first approximation may be simply the determined pressure drop divided by the flow immediately before the introduction of the occlusion.

[0009] A similar method is described in US 5,876,352 wherein is disclosed that a pressure drop is dependent effectively on a patient's lung resistance and that the compliance (resistance^{-1}) of the breathing circuit should be compensated for to improve the accuracy of the described method.

[0010] Since the determined pressure drop effectively results from the patient tube resistance then the known Blasius formula may then be used to provide, for a given gas flow, F, a link between the determined pressure drop, ΔP, and the resistance, R, of the breathing tube of length, L, and diameter, D, according to:

$$\Delta P = 0.24 \times (L/D^{4.75}) \times \mu^{0.25} \times \rho^{0.75} \times F^{1.75} \quad (1)$$

where μ and ρ are respectively the gas viscosity and the gas density.

[0011] Equation (1) may be re-written as:

$$\Delta P = K \times (L/D^{4.75}) \times F^{1.75} \quad (2)$$

which gives

$$\Delta P/F^{1.75} = K \times (L/D^{4.75}) = R \quad (3)$$

[0012] Thus by determining a pressure drop ΔP obtained at a flow value F, an indication of the effective resistance of the breathing tube can be obtained automatically during breathing assistance to avoid the need for user input of the information. In particular, from equation (3) a calculation of $\Delta P/F^{1.75}$ at a known flow or a

calculation of a value of a linear rate of change of ΔP with $F^{1.75}$,that is, $d\Delta P/dF^{1.75}$, may preferably be used to provide an indication of the tube resistance.

[0013] Moreover the resistance is an actual resistance which thus reflects the reality of the breathing circuit in use. This has the advantage that the method may be employed to monitor the breathing circuit during mechanical breathing assistance for changes in resistance which would indicate a leakage (decreased resistance) or a blockage (increased resistance) or may be employed to provide a resistance value of the actual breathing circuit which is used to compensate pressure measurements made by sensors in the breathing circuit.

[0014] Preferably, the occlusions are introduced during an expiration phase of a patient breathing cycle so as to reduce the effect of the evaluation method on breathing gas supply to the patient and so reduce any discomfort which the patient might otherwise experience.

[0015] Usefully, if the method is to be employed for a number of different gas flows, for example when calculating the flow dependent rate of change of pressure drop, that is either $d\Delta P/dF^{1.75}$ or $d\Delta P/dF$, then the different gas flows may be obtained by introducing the occlusions at different times within one or more expiration phases of a patient breathing cycle. Since the flow during an expiration phase varies with time then this has the advantage that the natural variation of flow with time over an expiration phase may be utilised to further reducing the adverse effects the use of the method of the present invention may have on the provision of mechanical breathing assistance.

[0016] Advantageously, the evaluation may be made at different times within a single expiration phase so that a calculation of flow dependent rate of change of pressure drop may be made in a single breathing cycle. Alternatively, if a calculation is to be made during an inspiration phase of a single breathing cycle then a ramped gas flow may be provided and occlusions similarly introduced throughout that phase.

[0017] According to a second aspect of the present invention there is provided an arrangement for carrying out the method according to the first aspect of the present invention.

[0018] An exemplary embodiment of an arrangement and methods of its working according to the present invention will now be described with reference to the drawings of the accompanying figures, of which:

Fig. 1 shows a schematic representation of an arrangement according to the present invention in operable connection with a mechanical breathing assist device;

Figs. 2 show a) gas flow characteristics during a volume control mode breathing cycle in which an occlusion is introduced as a breath-hold and b) corresponding gas pressure characteristics;

Figs.3 show a) gas flow characteristics during a pressure support mode breathing cycle in which an occlusion is introduced as a breath-hold and b) corresponding gas pressure characteristics;

Fig 4 shows the effect of tube diameter on effective resistance of a breathing tube evaluated according to the breath-hold technique of Figs. 2;

Figs. 5 show a) gas flow characteristics during a breathing cycle in which temporary occlusions are introduced throughout an expiration phase and b) corresponding gas pressure characteristics; and

Fig 6. shows an established relationship between pressure drops, ΔP, and gas flow, F evaluated according to the expiration occlusion technique illustrated in Figs 5.

[0019] Considering now Fig. 1, a patient ventilator 2 is shown interconnected with a breathing circuit 4 and a calculations unit 6 for evaluating an effective flow resistance within the breathing circuit 2 during the assisted ventilation of a patient.

[0020] The patient ventilator 2 comprises a gas flow control unit 8 which connects to an inspiration line 10 and an expiration line 12 of the breathing circuit 4 via, respectively, an inspiration valve 14 and an expiration valve 16 within the ventilator 2. Valve actuators 18,20 within the ventilator 2 are operably connected to a respective one of the inspiration valve 14 and the expiration valve 16 and operate on receipt of a control signal to open and close their associated valve 14,16. The flow control unit 8 is connected to the actuators 18,20 and is adapted to provide control signals thereto in order to regulate the flow of inspiration and expiration gases in a known manner to provide a mechanical breathing cycle having controllable inspiration and expiration phases during one or more known control modes of operation of the ventilator 2.

[0021] The patient breathing circuit 4 includes a Y-Piece 22, the separate limbs of which connect to the inspiration line 10 and the expiration line 12 and the common trunk of which connects to a small bore (typically between 5mm and 8mm) endotracheal tube 24. The endotracheal tube 24 has an open end 26 which, when breathing assistance is being provided by the ventilator 2, is inserted into the proximal airways of the patient.

[0022] The calculations unit 6 functionally comprises a control unit 28 and an operably connected processor unit 30 which has associated therewith a memory unit 32. It will be appreciated from the subsequent description of the operation of these units 28,30,32 that they may be formed by a suitably programmed micro-computer. The control unit 28 is connected external the calculations unit 6 to a sensor unit 34, to the gas flow control unit 8, to the valve actuators 18,20 and to an alarm unit 36.

[0023] The sensor unit 34 comprises both pressure and flow sensor elements and may be conveniently located within the common trunk of the Y-Piece 22 so as to be able to monitor pressures and flows of both inspiration and expiration gases within the breathing circuit 4. The sensor unit 34 is thus able to provide the control unit 28 (and optionally the gas flow control unit 8) with measured values of pressure and gas flow for either of the inspiration gas and the expiration gas as required.

[0024] The control unit 28 is additionally operable to provide control signals to the valve actuators 18,20 to open and close the associated valves 14,16 and thereby introduce a temporary occlusion to gas flow within the breathing circuit 4. This may be achieved either directly or via the flow control unit 8 which normally operates to control these actuators 18,20 to provide a patient breathing cycle during normal operation of the ventilator 2. The control unit 28 may also be adapted to provide these control signals in dependence of timing signals from the gas flow control unit 8 of the ventilator 2 which are synchronised with the inspiration and the expiration phases of the breathing cycle being provided by the ventilator 2.

[0025] In this manner valve components 14,18;20,16 which are typically already found in the patient ventilator 2 for controlling inspiration gas flow and expiration gas flow during a patient breathing cycle may be employed in the present invention. Alternatively a specific valve arrangement (not shown) may be used to introduce occlusions to gas flow and may be placed at the Y-Piece 22 to reduce the number of extra components.

[0026] During mechanical breathing assistance the effective flow resistance of the breathing circuit 4 may be evaluated as follows with reference to Figs. 2:

[0027] The gas flow control unit 8 of the ventilator 2 is arranged to provide in a volume control mode of operation a constant gas flow, F, to the patient during an inspiration phase, I. During this phase the inspiration valve 14 is open and the expiration valve 16 is closed under the control of the unit 8. At the end of an inspiration phase the unit 8 is instructed by the control unit 28 to also close the inspiration valve 14 and initiate a "breath-hold", B, at a time, T0, and of a duration typically between 1 ms to 200 ms. After a predetermined time the control unit 8 is instructed to operate to open the expiration valve 16 and an expiration phase, E, commences. The pressure, P1, as measured by the sensor unit 34 immediately before the breath-hold, B, is passed via the control unit 28 to the processor unit 30 where it may be stored in the memory 36 together with an associated gas flow value, F, as also measured by the sensor unit 34. The pressure measurement is repeated throughout the duration of the breath-hold and the "intermediate" pressure values are stored within memory 32 together with their associated times. A final pressure, P2, is recorded at a time, T2, at the end of the breath-hold and both values are again stored within the memory 32. The stored pressure and times are then accessed by the processor unit 30 which is adapted to calculate a pressure, P0, being extant within the breathing circuit 4 immediately upon introduction of the breath-hold at time, T0. This may be done by using the intermediate pressure and time values to obtain a gradient value with which to back-extrapolate the final pressure P2, extant at T2, to the time T0. The difference between the pressures immediately before (P1) and immediately after (P0) the breath-hold is taken to be the pressure drop ΔP resulting from the breathing circuit resistance, which is substantially due to the resistance of the endotracheal tube 24. The values ΔP and F are stored within the memory 32 and the process may be repeated at least once more with the flow control unit 8 operating to provide a different value of inspiration gas flow, F. The processor unit 30 then operates to recall the stored ΔP and F values and evaluate an effective flow resistance using these recalled values. The unit 30 may be programmed to determine a relationship between the pressure drop, ΔP, and the (obtained flow values, $F)^{1.75}$, such as by calculating a value of a linear rate of change of determined pressure drop with (obtained flow value)^{1,75} . This value, as can be seen from equation (3) above, provides a measure of the effective resistance of the breathing circuit 4.

[0028] It will be appreciated that the breath-hold technique may be applied in other operating modes of the ventilator 2. An example of this is provided for a pressure support mode of operation and is illustrated in Figs. 3 in which features common with Figs. 2 are given the same reference labels. During pressure support mode the ventilator 2 is operated in a known fashion to support a patient's breathing effort by supplying breathing gas upon receipt of a trigger signal from the sensors in the sensor unit 34 indicative of a patient attempting to breathe. Fig. 3a illustrates a typical flow characteristic over one breath during pressure support and shows a varying flow during inspiration, I. The breath hold, B, is initiated based on an average of previous, typically three, breaths. The unit 8 operates to close flow valves 14,16 at a time T0 when a measurable quantity, such as inspiration time, inspiration flow, delivered volume, or inspiration pressure, in the present breath reaches a threshold based on the aforementioned average breath. Such a criteria for initiation a breath hold may be when the delivered volume reaches 90% of the expected total delivered volume based on an average of three preceding breaths. The calculations unit 6 then operates as described above with regard to the volume control mode of Figs. 2 to measure a final pressure, P2, at the end of the breath hold at time T2 and to extrapolate back to determine a pressure P0 at time T0. The pressure drop, ΔP, being P1-P0, is calculated and a tube resistance, R, may be determined from equation (3) above. Indeed if only an indication of tube resistance is required, for example if monitoring for changes in measured resistance, then a relationship of $\Delta P/F$ need only be determined.

[0029] The effect of breathing tube internal diameter

on the calculated pressure drop, ΔP, as determined from breath-hold measurements described above. is shown in Fig. 4 for different inspiration flows, F. The relationship is shown in Fig. 4 as a plot of ΔP with $F^{1.75}$.

[0030] Additionally or alternatively the effective flow resistance of the breathing circuit 4 may be evaluated during on or more expiration phases of mechanical breathing assistance such as during a single expiration phase as shown with reference to Figs. 5.

[0031] The gas flow control unit 8 of the ventilator 2 is arranged to control the gas flow through the breathing circuit 4 to provide the patient with a breathing cycle comprising an inspiration phase, I and an expiration phase, E, with or without a breath-hold, B, according to the requirements of the patient. After the inspiration phase, I, the unit 8 operates to close the inspiration valve 14 and open the expiration valve 16 in order to provide an expiration phase, E. At the same time a trigger signal is passed from the flow control unit 8 to the control unit 28 of the calculation unit 6 to indicate the onset of the expiration phase, E. After a predetermined time (or flow as measured by the sensor unit 34) the control unit 28 operates to supply a signal to the actuator 20 to close the expiration valve 16 and an initiate an occlusion, O, to the flow of gas through the breathing circuit 4. A pressure, P1, as measured by the sensor unit 34 is passed via the control unit 28 to the processor unit 30 where it may be stored in the memory 36 together with an associated gas flow value, F1, as also measured by the sensor unit 34. A short time later (1ms to 200ms) the control unit 28 controls the actuator 20 to open the expiration valve 16 and remove the occlusion. At this time second pressure, P1', as measured by the sensor unit 34 is passed via the control unit 28 to the processor unit 30 which can then calculate a value of a pressure drop $\Delta P1$ (P1-P1') which is stored in memory 32 together with the flow value F1. These steps may be repeated at least once during the expiration phase, E, and pressure drops $\Delta P2$, $\Delta P3$ calculated and stored in memory 32 together with their associated flow values F2, F3. Alternatively, if more than one pressure drop ΔP is to be used to establish the relationship then at least one other expiration phase, E, may be employed in at least one other breath. The occlusion, O, is then introduced at a different predetermined time or measured flow.

[0032] The processor unit 30 may be adapted to recall the stored ΔP and F values and evaluate an effective flow resistance using these recalled values as described above in relation to the breath-hold process. Additionally or alternatively the processor unit 30 can be adapted to establish a relationship between the pressure drops and flow values as an evaluation of the effective flow resistance by constructing a digital representation of the pressure drop(ΔP)/flow(F) curve illustrated in Fig. 6. The processor unit 30 can be programmed to establish a "best-fit" to the so determined curve using either previously stored curves for breathing tubes of known internal diameter or calculated using equation (3). The value of the breathing tube diameter giving the best fit can then be used by the gas flow control unit 8 of the ventilator 2 during the provision of breathing assistance to compensate measured pressures for the effects of the breathing tube resistance.

Claims

1. A method for evaluating an effective flow resistance of a breathing circuit (4) during mechanical breathing assistance **characterised by** the steps of:

   introducing a temporary occlusion (B;O) to gas flow (F) within the breathing circuit (4) during a patient breathing cycle;
   obtaining a value of the gas flow (F) extant at the introduction of the occlusion (B;O);
   determining a value of a pressure drop (ΔP) within the breathing circuit (4) consequent on the introduction of the occlusion (B;O); and
   evaluating the effective flow resistance (R) by establishing a relationship between the determined pressure drop (ΔP) and the obtained flow value (F).

2. A method as claimed in claim 1 **characterised in that** establishing the relationship comprises establishing a value of determined pressure drop (ΔP) divided by [obtained flow value]^{1,75}.

3. A method as claimed in Claim 1 or Claim 2 **characterised in that** the steps of:

   introducing a temporary occlusion (B;O); of
   obtaining a value of the gas flow (F); and of
   determining a value of a pressure drop (ΔP) within the breathing circuit (4) consequent on the introduction of the occlusion (B;O);
   are repeated at least once with a different gas flow.

4. A method as claimed in Claim 3 **characterised in that** establishing the variation comprises calculating a value of a linear rate of change of determined pressure drop (ΔP) with [obtained flow value]^{1,75}.

5. A method as claimed in any preceding Claim **characterised in that** determining the pressure drop (ΔP) comprises measuring a circuit pressure (P1) extant within the breathing circuit (4) before the introduction of the occlusion (B) and a circuit pressure (P2) extant at the end of the occlusion (B);
   back extrapolating the pressure (P2) extant at the end of the occlusion (B) to determine a pressure (P0) at the introduction of the occlusion (B); and
   subtracting the determined pressure (P0) from the measured circuit pressure (P1) extant before the in-

troduction of the occlusion (B).

6. A method as claimed in any preceding Claim **characterised in that** introducing the occlusion comprises initiating a breath-hold (B) at the end of the inspiration phase (I).

7. A method as claimed in any of the Claims 1 to 5 **characterised in that** introducing the occlusion (O) comprises occluding the flow during an expiration phase (E) of a breathing cycle.

8. An arrangement for evaluating an effective flow resistance (R) of a breathing circuit (4) connected to a mechanical breathing assist device (2), the arrangement comprising:

a flow controller (8,28) operable to temporarily introduce an occlusion (B;O) to gas flow (F) within the breathing circuit (4) at a time after the end of an inspiration phase (I) of a breathing cycle provided by the breathing assist device (2); a flow sensor (34) for measuring gas flow within the circuit (4) ;
a pressure sensor (34) for measuring gas pressures within the circuit (4); and
an evaluating unit (6) adapted to receive measurements from the sensors (34), to determine for a measured gas flow (F) a value of a pressure drop (ΔP) within the breathing circuit (4) consequent on the introduction of the occlusion (B;O) and to establish a relationship between the calculated pressure drop (ΔP) and the measured gas flow (F).

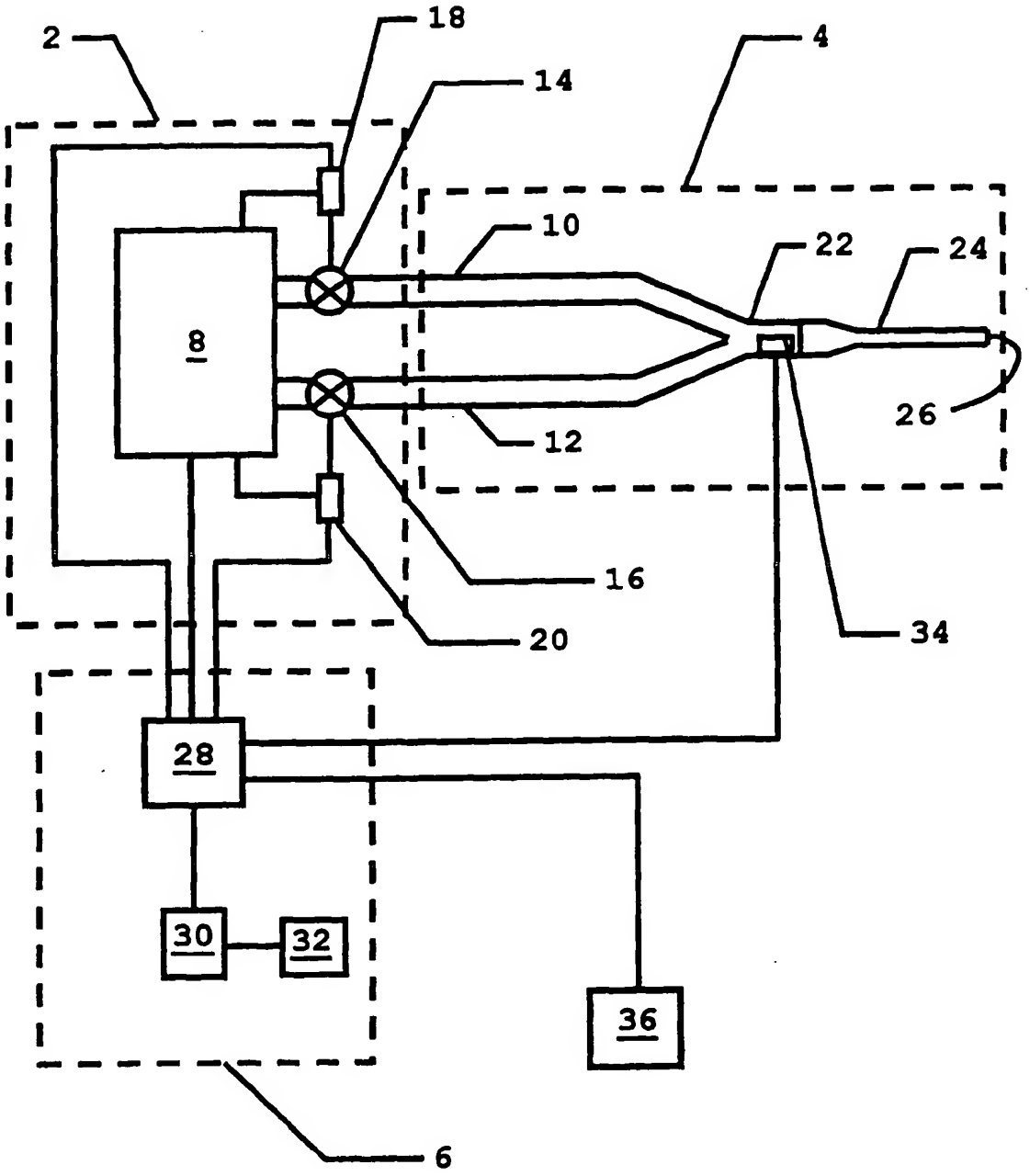
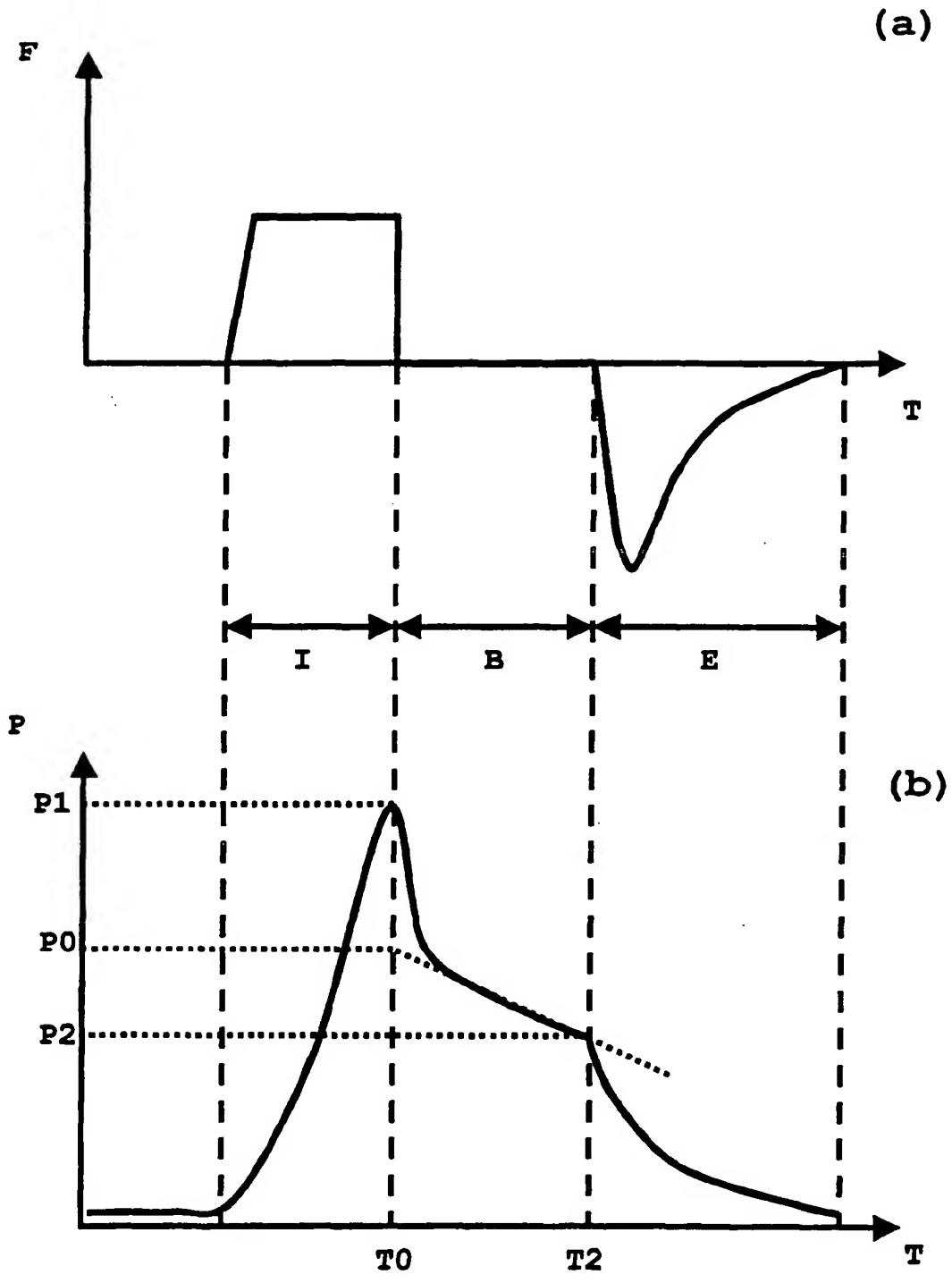
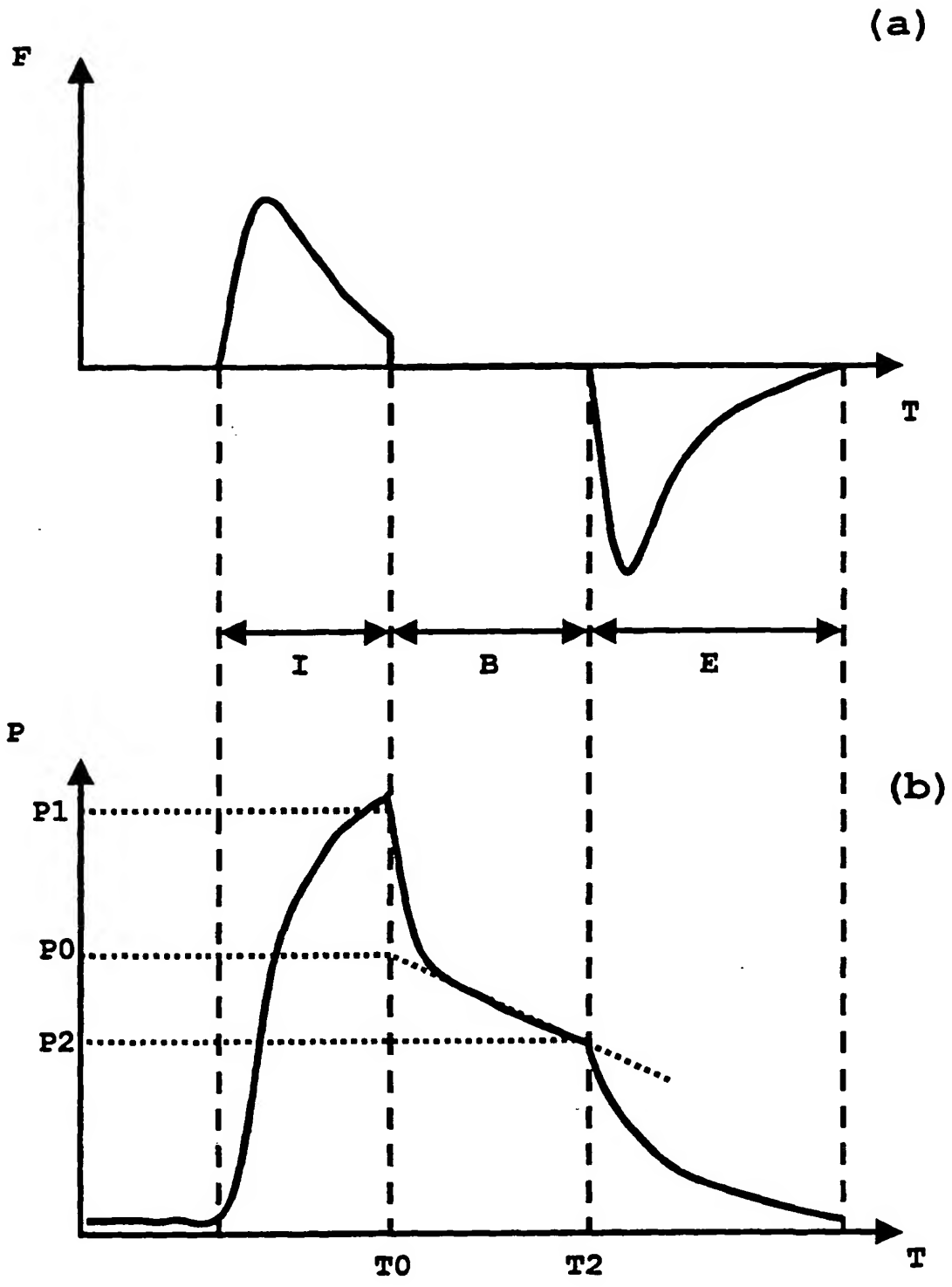


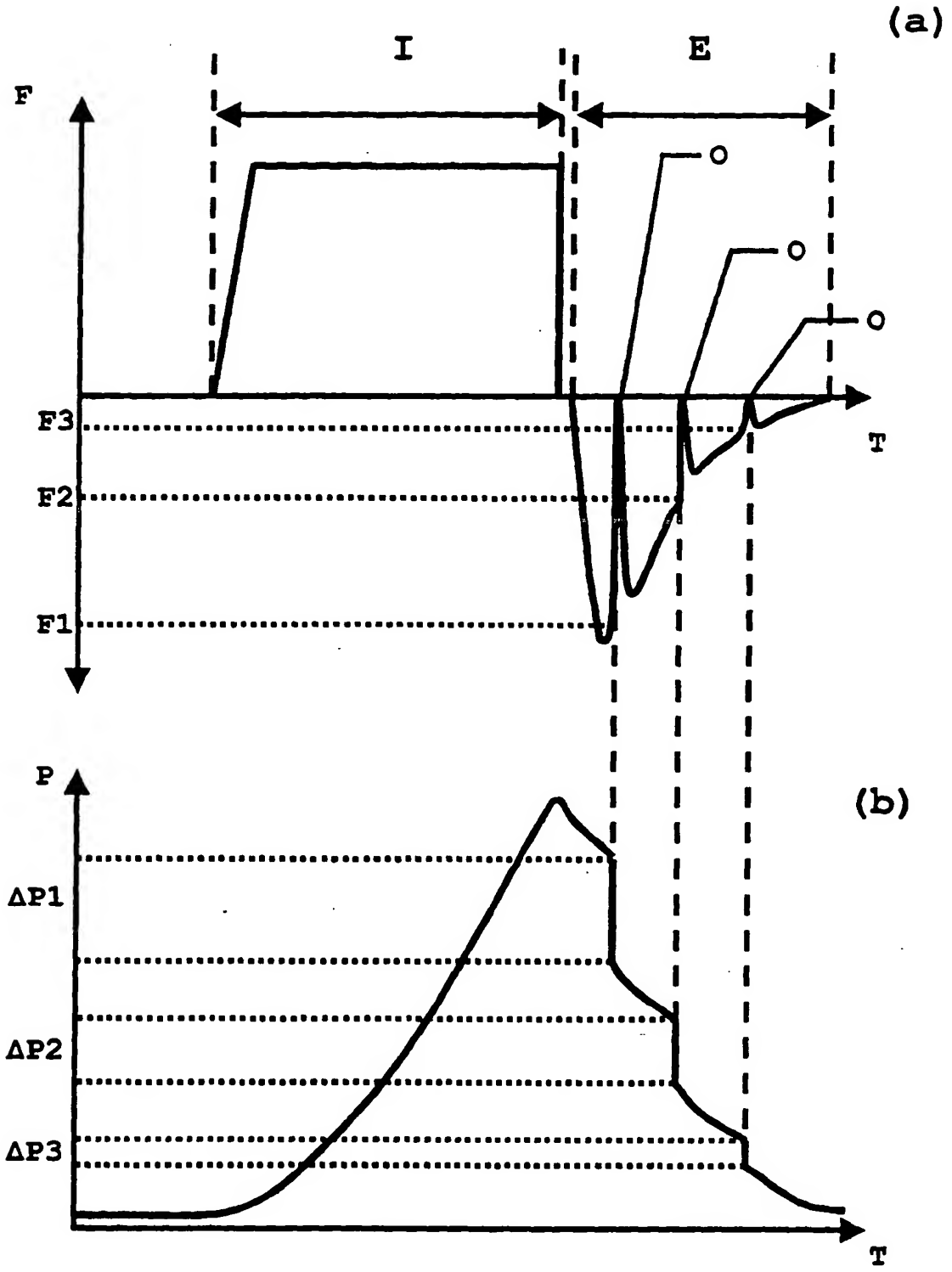
Fig. 1



Figs. 2



Figs. 3



Figs. 5

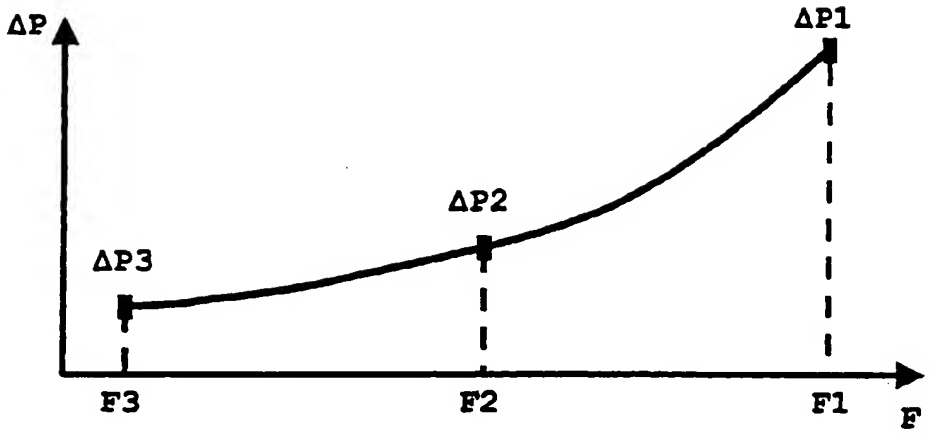

ΔP
ΔP1
ΔP2
ΔP3
F3
F2
F1
F

Fig. 6

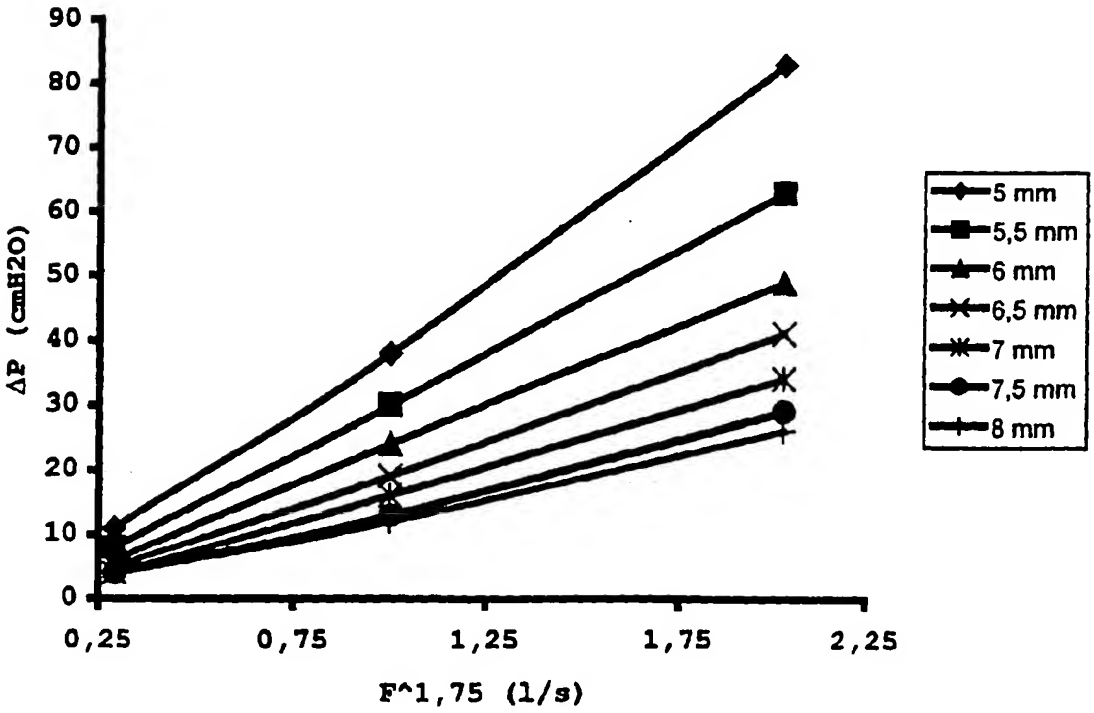

90
80
70
60
50
40
30
20
10
0
ΔP (cmH2O)
0,25
0,75
1,25
1,75
2,25
F^1,75 (l/s)
5 mm
5,5 mm
6 mm
6,5 mm
7 mm
7,5 mm
8 mm

Fig. 4

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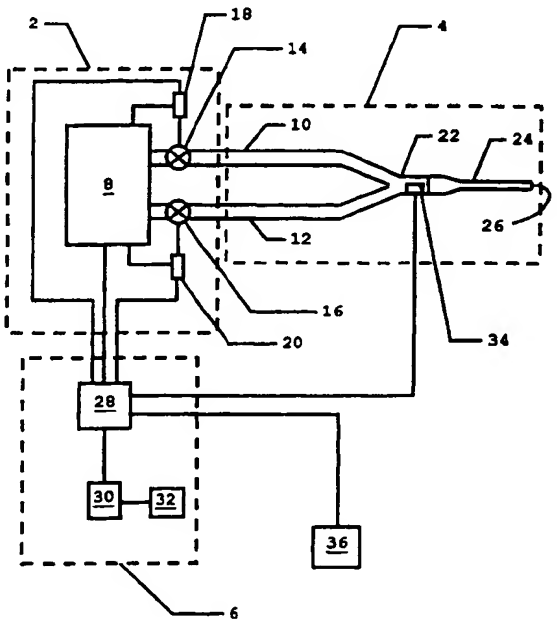

Fig. 1

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European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 01 11 0606

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 5 876 352 A (WEISMANN DIETER) 2 March 1999 (1999-03-02) * column 4, line 1-5 * * column 5, line 12-62 * * column 6, line 15-55 * * figures 1-3,7 * ---	8	A61M16/00
A	EP 0 419 113 A (MICRO MEDICAL LTD) 27 March 1991 (1991-03-27) * column 2, line 47 - column 4, line 18 * * figures 1-3 * ---	8	
A	DE 197 34 203 A (GREINER WOLFGANG DR ;SCHUMANN KLAUS (DE); REICHERT EBERHARD DR (DE) 25 February 1999 (1999-02-25) * column 2, line 58 - column 4, line 46 * * column 4, line 56-60 * * figures 1,3,4 * -----	8	

TECHNICAL FIELDS SEARCHED (Int.Cl.7)

A61B
A61M

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

8

Claims searched incompletely :

Claims not searched :

1-7

Reason for the limitation of the search:

Article 52 (4) EPC - Diagnostic method practised on the human or animal body
Article 52 (4) EPC - Method for treatment of the human or animal body by therapy

Place of search	Date of completion of the search	Examiner
MUNICH	20 May 2003	Azaïzia, M

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 01 11 0606

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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20-05-2003

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